DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 6, 2016

SunTech Medical, Inc.
Chuck Setzer
Quality & Regulatory Affairs Manager
507 Airport Blvd
Suite 117
Morrisville, North Carolina 27560

Re: K160439
Trade/Device Name: SunTech CT40 Spot-check Vital Signs Device (Model 260)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 3, 2016
Received: June 7, 2016

Dear Chuck Setzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160439

Device Name
CT40 Vital Signs, Spot Check Vital Signs Device

Indications for Use *(Describe)*

The SunTech CT40 (Model 260) is a non-invasive oscillometric spot check vital signs device. The CT40 is capable of measuring and displaying brachial systolic and diastolic blood pressure, heart rate, percent oxygenated hemoglobin (SpO2) and body temperature on children 3 years of age to adults. This device is intended for use by a qualified clinician when it is necessary to take one or more vital signs measurements on a patient. The CT40 is only for measurement, recording, and display. It makes no specific diagnoses.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SunTech Medical, Inc.
Abbreviated 510(k) Submission
CT40 (Model 260)
510(k) Summary

(1) Submitter information

Name:	SunTech Medical, Inc
Address:	507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200
Telephone:	919.654.2334
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Contact person:	Charles Setzer (Official Correspondent). SunTech Medical 507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200 Tel: 919-654-2334 Fax: 919-654-2301
Date prepared:	February 12, 2016

(2) Name of Device

Trade Name:	CT40; Model 260; CT40 Spot-check Vital Signs Device
Common Name:	NIBP, SpO2 and Temperature Device
Classification name:	Noninvasive Blood Pressure Measurement System, DXN 870.1130

(3) Legally-marketed predicate devices

The CT40 (Model 260) is an updated version of SunTech's 247 Spot Check Device (**K070750**). It includes the same measurement parameters, NIBP, SpO2 and temperature, as the 247 device.

The new CT40 (Model 260) has the same intended use of the 247 device. Both the CT40 and 247 devices have NIBP as a standard parameter and have optional SpO2 and Temperature modules that can be added if desired.

The CT40 also includes a touch-less IR thermometry option that the 247 does not have. For this added temperature option the Spot Vital Signs LXi by Welch-Allyn Inc. [**510k # K101680**] is used as a predicate device.

(4) Description

The CT40 (Model 260) is designed to non-invasively measure systolic and diastolic blood pressure, pulse rate, temperature, and oxygen saturation (SpO2) for adult and pediatric patients. All blood

pressure, pulse, temperature, and SpO2 values are displayed on a large, easy-to-read LCD. The device has a rechargeable battery and may be use as a desktop unit or on a mobile stand.

The CT40 (Model 260) Spot-check Vital Signs Device can perform automatic blood pressure, pulse oximetry and body temperature measurements for clinical professionals. The CT40 (Model 260) consist of a base unit with NIBP, display, control buttons and knob housed in an ABS plastic enclosure. The left side of the unit has a removable panel were a SpO2 module may be connected. And the right side of the unit has a removable panel where a temperature module may be connected.

For measuring blood pressure, a blood pressure cuff is placed around the patient's non-dominant upper arm. The cuff is automatically inflated and the blood pressure is determined by the oscillometric method, which senses pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves enables heart rate to also be measured.

The pulse oximetry function non-invasively measures the patient's percent oxygen saturation of arterial hemoglobin using principles of plethysmography via a SpO_2 sensor placed on the patient's finger.

Temperature can be measured using one of two different kinds of temperature technology. The oral/axillary/rectal temperature probe contains a thermistor that generates a voltage based on changes in temperature, and these voltages are measured by the temperature circuitry. The touchless infrared temperature probe detects radiated infrared energy from the temporal artery.

The CT40 (Model 260) is a portable device, approximately 205 x 190 x 140 mm in size and weighs approximately 1440 g without battery. Control buttons allow the user to stop/start a BP measurement, save a set of measurements to memory, change between BP modes, and return to the home screen.

There is also a selection knob that is used to scroll and select different device options. The backlit LCD display shows the user device status and measurement information. The device uses a microprocessor with firmware, which is not accessible to the user. The unit is powered by AC mains power and rechargeable lithium-ion battery. Two USB-A port connections can be used to connect, an optional printer, barcode scanner or Wi-Fi dongle. There is also RJ11 Ethernet port for network connectivity, and a mini-USB port used to connect the device to a PC or laptop for advanced device configuration.

An Abbreviated 510(k) is necessary because the CT40 (Model 260) uses recognized standards for establishing safety and effectiveness.

(5) Intended Use

The SunTech CT40 (Model 260) is a non-invasive oscillometric spot check vital signs device. The CT40 is capable of measuring and displaying brachial systolic and diastolic blood pressure, heart rate, percent oxygenated hemoglobin (SpO_2) and body temperature on children 3 years of age to adults. This device is intended for use by a qualified clinician when it is necessary to take one or

more vital signs measurements on a patient. The CT40 is only for measurement, recording, and display. It makes no specific diagnoses.

(6) Indications for Use

The SunTech CT40 (Model 260) is a non-invasive oscillometric spot check vital signs device. The CT40 is capable of measuring and displaying brachial systolic and diastolic blood pressure, heart rate, percent oxygenated hemoglobin (SpO_2) and body temperature on children 3 years of age to adults. This device is intended for use by a qualified clinician when it is necessary to take one or more vital signs measurements on a patient. The CT40 is only for measurement, recording, and display. It makes no specific diagnoses.

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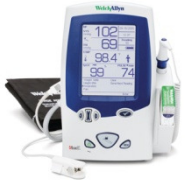
(7) Comparison to Predicate Devices

The device has similar construction as the primary and secondary predicate device. The primary device shares the similar specifications, measurement ranges and intended uses. The devices are manufactured from the same types of materials using the same production methods and are intended for the same patient populations.

Characteristic	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE
	SunTech Medical Inc. CT40 (Model 260)	SunTech Medical Inc. 247 (Model 247B) (K070750)	Welch-Allyn Spot VITAL SIGNS LXi (K101680)
System Photo			

Characteristic	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE
	SunTech Medical Inc. CT40 (Model 260)	SunTech Medical Inc. 247 (Model 247B) (K070750)	Welch-Allyn Spot VITAL SIGNS LXi (K101680)
Indications for Use	The SunTech CT40 (Model 260) is a non-invasive oscillometric spot check vital signs device. The CT40 is capable of measuring and displaying brachial systolic and diastolic blood pressure, heart rate, percent oxygenated hemoglobin (SpO_2) and body temperature on children 3 years of age to adults. This device is intended for use by a qualified clinician when it is necessary to take one or more vital signs measurements on a patient. The CT40 is only for measurement, recording, and display. It makes no specific diagnoses.	The SunTech Medical 247 NIBP, Temperature, and Pulse Oximeter device is indicated for use in measuring and displaying Systolic and Diastolic blood pressures, heart rate, temperature, and functional saturation of arterial hemoglobin (SpO_2) of adult and pediatric patients in hospitals, medical facilities, clinics, physicians offices, and other sub acute environments.	Same as CT40 (Model 260) Except Spot VITAL SIGNS LXi includes Body Mass Index calculator that requires the manual input of weight, height, respiration rate and pain level. And the Spot VITAL SIGNS LXi has NIBP and Temperature as standard feature and SpO2 as an option. The Spot VITAL SIGNS LXi displays MAP and the CT40 does not.
Target Population	The CT40 (Model 260) device is intended to be used on adult and pediatric patients over the age of 3 yrs.	Same	Same
Location of Use (primary)	Physician's office, clinic, research center (*under supervision of physician*)	Same	Same
NIBP Modes of Operation	Automated Oscillometric NIBP	Same	Same
SpO2 Pulse Oximetry Options	ChipOx from Corscience (Nellcor® compatible) Masimo®	ITEC (Nellcor® compatible)	Masimo® Nellcor®

Characteristic	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE
	SunTech Medical Inc. CT40 (Model 260)	SunTech Medical Inc. 247 (Model 247B) (K070750)	Welch-Allyn Spot VITAL SIGNS LXi (K101680)
Body Temperature options	Covidien® Fast Temp or HuBDIC® IR Temp	Covidien® Fast Temp	Welch Allyn SureTemp® Plus or Braun ThermoScan® PRO 4000 IR Temperature
Materials	Materials and construction are the same as the 247 device except: Updated electronics, LCD display replaces LED display	ABS plastic	Similar enclosure and display. User interface is similar but configuration is slightly different.
Biocompatibility Patient contact	1. BP Cuff: Same as SunTech 2. SPo2 Sensor 1: Same as SunTech 3. Spo2 Sensor 2: Same as Welch Allyn (Massimo) 4. Temp Probe: Same as SunTech	1. BP Cuff: SunTech OPD 2. SPo2 Sensor 1: UniTech 3. Spo2 Sensor 2: Massimo 4. Temp Probe: Covidien	1. BP Cuff: Welch Allyn 2. SPo2 Sensor 1: Nellcor 3. Spo2 Sensor 2: Massimo Temp Probe: Welch Allyn
Human Factors	More complex than SunTech 247. Similar complexity to Welch Allyn.	Simple 2 button interface. No	
Power	Mains Power 100-240 VAC, 50-60Hz Supply & Rechargeable 7.2V Lithium Ion Battery	Mains Power 100-240 VAC, 50-60Hz Supply & Rechargeable 6V SLA Battery	Mains Power 100-240 VAC, 50-60Hz Supply & Rechargeable 6.4 V Lithium Ion Battery
Blood Pressure Range	Systolic: 40 - 260 mmHg Diastolic: 25 - 200 mmHg	Systolic: 60 - 270 mmHg Diastolic: 30 -170 mmHg	Systolic: 60 - 250 mmHg Diastolic: 30-160 mmHg

Characteristic	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE
	SunTech Medical Inc. CT40 (Model 260)	SunTech Medical Inc. 247 (Model 247B) (K070750)	Welch-Allyn Spot VITAL SIGNS LXi (K101680)
Measurement	Same	Determines brachial BP from oscillometric waveform pulses captured during deflation of the cuff. The key clinical parameters are: 1. Systolic and Diastolic Blood Pressure 2. Heart Rate 3. Temperature 4. $Sp0_2$	Determines brachial BP from oscillometric waveform pulses captured during deflation of the cuff. The key clinical parameters are: 1. Systolic and Diastolic Blood Pressure 2. Heart Rate 3. Temperature 4. $Sp0_2$
Performance	NIBP, ChipOx SpO2 and Covidien temperature are the same as SunTech 247. Massimo SpO2 is the same as Welch Allyn. HuBDIC IR temperature is similar to Welsh Allyn IR Temperature.		
External connections	1. 2 USB-A connections 2. 802.11 a,b,g, wireless communications 3. Ethernet RJ45 connector 4. Micro USB	None	1. 2 serial DB9 connectors 2. 802.11 a,b,g, wireless communications 3. Mini USB
External Connection Devices	1. Bar code Scanner 2. Future option for Printer 3. Connectivity to Hospital EMR	None	1. Weight Scales 2. Connectivity to Hospital EMR

(8) Testing and Validations

The CT40 (Model 260) has been tested to the applicable requirements of the following standards and requirements documents. These tests have indicated passing results.

- IEC 60601-1: 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-6: 2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 80601-2-30: 2009 +A1: 2013, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 81060-2: 2013, Non-invasive sphygmomanometers —Part 2: Clinical investigation of automated measurement type
- ISO 80601-2-56: 2009 Medical electrical equipment – Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
- ISO 80601-2-61: 2011 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC62304:2006 Medical device software – Software life cycle processes
- IEC62366:2008 Medical devices - Part 1: Application of usability engineering to medical devices

Non-Clinical testing

Output Document	Description
99-0131-XX-HQ3	System Level Test Report / system level test cases and test results.
99-0131-XX-HQ4	Software Test Report / software test cases and test results.
99-0131-XX-HQ5	Hardware Test Report / hardware test cases and test results.
99-0131-XX-HQ6	Mechanical Test Report / mechanical test cases and test results.
99-0131-XX-SVR_Wireless	Software Validation Report, Wireless
97-0143-XX-CV-81060-2	NIBP Clinical Validation Study
80-0067-00-MO	CT40 User Manual

(9) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, SunTech Medical concludes that the CT40 (Model 260) is safe, effective and substantially equivalent to the predicate devices described herein.